U.S. Access Board

Prescription Drug Container Labels

The Board has led the development of advisory guidance on making prescription drug container labels accessible to people who are blind or visually impaired or who are elderly. This initiative was authorized by the Food and Drug Administration Safety and Innovation Act *(https://www.access-board.gov/rx/fda-section-904.html)* which President Obama signed into law in July 2012. A provision of the act (section 904) directs the Board to convene a working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually impaired.

Shortly after the law was enacted, the Board formed the Working Group on Accessible Prescription Drug Container Labels, an 18-member stakeholder panel comprised of representatives from advocacy organizations and industry. The working group explored various access alternatives, including braille, large print labels, and auditory technologies such as "talking bottles" and radio frequency identification tags. In July 2013, it submitted to the Board its best practice recommendations *(#working-group-recommendations)* for pharmacies on providing independent access to prescription drug container labels. These recommendations are advisory only, not mandatory, and will not have the force of guidelines or standards.

BEST PRACTICES FOR ACCESSIBLE PRESCRIPTION DRUG LABELING:
Pharmacies have a critical role to play to ensure the safety of blind, visually impaired, and elderly customers

The law directed the National Council on Disability (NCD) to conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. In June 2016, NCD issued a brochure *(http://www.ncd.gov/publications/2016/best-practices-accessible-prescription-drug-labeling)* on the best practices recommended by the Board's working group. The law also called upon the Comptroller General to conduct a review to assess the extent to which pharmacies are implementing the best practices and to determine whether barriers to prescription drug labels remain; the report *(https://www.gao.gov/products/GAO-17-115)* was completed in December 2016.

Several national pharmacy chains now offer talking prescription information for blind customers: CVS (including its mail service company Caremark), Walmart and Sam's Club, Walgreens, Rite Aid, and Express Scripts Pharmacy.

On March 18, 2014, CVS announced that it is providing ScripTalk talking prescription labels to customers with visual impairments ordering through cvs.com. The CVS initiative will ensure that cvs.com customers who are blind can access the critical health and safety information provided in a standard print prescription label. The Access Board Working Group's Final Report *()* Regarding Best Practices for Making Prescription Drug Container Label Information Accessible to Persons who are Blind or Visually-Impaired is referenced in section 3.2 and 3.5 of the agreement that led to the announcement. The agreement and announcement is the result of Structured Negotiations between CVS and the American Council of the Blind, the California Council of the Blind and the American Foundation for the Blind.

Working Group Recommendations

Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly

Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

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Legislative Background:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, 126 Stat. 993). The law includes measures to promote drug safety and to improve FDA procedures for reviewing new medicines and medical devices.

A provision of the Act, Section 904 *(https://www.access-board.gov/rx/fda-section-904.html)* , authorizes the Access Board to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly. (See 29 U.S.C. 792.) Under the law, representation within the working group must be divided equally between consumer and industry advocates. The Act exempts the working group from the Federal Advisory Committee Act.

The law calls for the working group to develop, no later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

According to Section 904, the best practices are not mandatory. They are not to be construed as accessibility guidelines or standards of the Access Board, nor do they confer any rights or impose any obligations on working group participants or other persons. The law makes it clear that nothing in Section 904 is to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

The law also provides that the working group may make this best practices report publicly available through the internet websites of working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities. The National Council on Disability will conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. The Government Accountability Office will undertake a review beginning 18 months after the date of this report to assess the extent to which pharmacies are following the best practices and to what extent barriers to information on prescription drug container labels remain.

Working Group Participant Organizations

In October 2012, the Access Board formed an 18-member working group with representation from national organizations advocating for individuals who are blind, visually-impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

The working group is comprised of representatives of the following organizations:

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Federation of the Blind (NFB)
- National Council on Patient Information and Education (NCPIE)
- Rite-Aid
- Target
- US Pharmacopeia (USP)

- Walgreens
- Wal-Mart

The working group met in person in Washington, DC, on January 10 and11, 2013, and subsequently via five teleconferences. The working group explored various alternatives, including braille, large print labels, and various auditory technologies such as “talking bottles” and radio frequency identification devices. The working group also considered whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices.

Why Are Best Practices Needed?

Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.

In recent years, various organizations, including US Pharmacopeia (USP), the National Association of Boards of Pharmacy, and the National Council on Patient Information and Education, have recommended the adoption of patient-centered pharmacy practices to improve patient understanding and safe, effective use of prescription medication. Inherently inclusive, patient-centered pharmacy practices promote accessibility, while a one-size-fits-all approach typically creates barriers.

In the context of this report, the term “best practice” refers to a set of working methods that the working group believes is most effective in providing access to prescription drug container label information to customers with blindness and visual impairments, including older adults.

The goal of the best practices for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

What Is a Prescription Drug Container Label?

A prescription drug container label is a legal document that must be prepared by the pharmacist filling the prescription. The pharmacist must ensure the accuracy of the prescription drug container label, and include on the label all elements required by applicable state law.

In 2009, USP determined optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription drug container label instructions. USP created universal prescription drug container label standards for format, appearance, content, and language (see: U.S. Pharmacopeial Convention *(https://www.access-board.gov/rx/pharma-convention.html)*). The best practices in this report build upon the USP universal patient-centered prescription drug container label standards.

Delivery Methods for Providing Accessible Prescription Drug Container Labels

A variety of delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats. Delivery methods include:

- Hard copy braille and large print: A pharmacist filling prescriptions produces hard copy braille and large print labels upon request, and affixes the accessible labels to the prescription drug containers.
- Dedicated electronic equipment: Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include:
    - Digital Voice or Text-to-Speech Recorder: This is a small electronic device that a pharmacist affixes to a prescription drug container. When activated by pushing a button on the device, the patient hears the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
    - Radio Frequency Identification Device (RFID): A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that, when a container with an RFI Tag is placed over the

device, audibly announces the text on the prescription drug container label. This technology may also provide prescription drug container label information in large print, and has a USB drive.

- Smart devices and computers: Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug container a QR code, RFI tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in electronic braille, large print, or audible format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

Some electronic prescription drug container label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate prescription drug container label information into several languages.

The key to providing accessible prescription drug container labels is patient-centered communication between pharmacists and patients with blindness and visual impairment and patient representatives. Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

Best Practices to Use for All Formats

The following best practices promote access to prescription drug container label information in all formats, including audible, braille, and large print labels.

- One of the best things pharmacists can do is to encourage patients and patient representatives to communicate their needs to pharmacists:
  - Advertise a local or, when possible, a toll-free telephone number to promote communication between patients and pharmacists;
  - If pharmacy websites and applications (apps) are made available to patients, ensure website and app accessibility; and
  - When a pharmacist observes a patient or patient representative having reading difficulty, offer education and counseling in a setting that maintains patient privacy.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print formats via methods using, for example, hard copy, dedicated devices, and computers or smart devices.
- Explain to the patient the available accessible prescription drug container label format options, and provide the prescription drug container label in the format option selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription drug container label.
- Subject accessible prescription drug container labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.
- In advance, make arrangements to provide accessible prescription drug container labels. For example, maintain a sufficient inventory of supplies necessary to support timely provision of prescription drug container labels in accessible label formats.
- Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments.
- Do not impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label.
- Select a container that best supports the type of accessible label provided.
- For all accessible label formats, including audible formats, ensure that all required information contained on the print prescription drug container label is provided on the accessible label in the same sequence as the print label.
- Include in accessible prescription drug container labels the information on warning labels added to the container at the pharmacist's discretion.

Format-Specific Best Practices

In addition to the best practices listed above, please note the following format-specific best practices.

Audible Prescription Drug Labels

For dedicated equipment, select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.

If using a voice recorder:

- speak in a clear voice;
- record information in a setting that minimizes background noise and maintains patient privacy.

Offer to show the patient how to operate the audible prescription drug container label.

Braille Prescription Drug Container Labels

Electronic delivery method: Acquire an electronic delivery method using RFI tags, QR codes, or other processes to provide electronic text of the prescription drug container label upon request. Consumers with electronic braille equipment may then access electronic text in braille format.

Note that, as required, the working group considered significant challenges that pharmacies may face in producing drug labels in accessible formats, such as hard copy braille. The working group recognizes that mail order and online pharmacies, because of their centralized structure, large volume, and mail delivery process, may be better equipped than local stores to provide hard copy braille prescription drug container labels. Many mail order and online pharmacies have established a unit with the necessary computer software and braille embossers to produce hard copy braille labels and a protocol to develop pharmacists' proficiency in printing accurate braille labels.

- If a local pharmacy store has a high demand for hard copy braille prescription drug container labels, acquire on-site braille embosser capacity and proficiency.
- If a local pharmacy store receives infrequent or occasional requests for hard copy braille prescription drug container labels, partner with a pharmacy that has braille prescription drug container labeling capacity to provide a hard copy braille prescription drug container label.

When embossing hard copy braille prescription drug container labels:

- Use contracted (Grade 2) braille.
- Emboss braille labels on transparent material in order to preserve the legibility of print container labels. Affix braille label to the prescription drug container with strong adhesive.
- Do not fold braille labels.

Printing Large Print Labels (hard copy):

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, san-serif font, such as Arial.
- Provide 1.5 line spacing.
- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.
- When covering a large print label with protective tape, use non-glossy, transparent tape.

Resources

USP Patient-Centered Prescription Label Standards *(https://www.access-board.gov/rx/pharma-convention.html)*

UMS White Paper, The National Council for Prescription Drug Programs Work Group (WG), 2013

Working Group Participant Organizations

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- Blinded Veterans Association (BVA)
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- Express Scripts
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